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Rejection of Claims - 35 U.S.C. § 103(a)

The rejection of Claims 1-17 under 35 U.S.C. 103(a) as being unpatentable over McCormick and Familo, *et al.*, further in view of Mehta, *et al.* is being maintained.

In the Office Action, the Examiner stated that Applicant has asserted that the claimed invention broadly relates to a staining procedure for a biological specimen that uses a corrosive reagent such as chromic acid; that Applicant has further asserted that the prior art does not teach of a staining protocol that uses a corrosive agent and therefore does not anticipate the claimed invention. The Examiner stated that Applicant's arguments have been carefully considered but not deemed persuasive. The Examiner stated that McCormick and Familo, *et al.* disclose a method of histological staining performed by an automated histological staining instrument and that the prior art differs from the claimed invention in that it does not teach of a histological staining process wherein the process includes Grocott's modification of Gomori's methenamine silver method. The Examiner stated that Mehta, *et al.* teach of a histological staining process wherein the process includes Grocott's modification of Gomori's methenamine silver method. The Examiner stated that given that 1) McCormick and Familo, *et al.* have taught of a method of histological staining performed by an automated histological staining instrument and that 2) Mehta, *et al.* have taught of a histological staining process wherein the process includes Grocott's modification of Gomori's methenamine silver method, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use an automated histological staining instrument and incorporate a staining process such as Grocott's modification of Gomori's methenamine silver method. The Examiner stated that one would have been motivated to use a histological staining process such as Grocott's modification of Gomori's methenamine silver method because such a staining method is commonly used and well known to those skilled in the art.

To clarify, Applicant has asserted, as also noted by the Examiner, that neither McCormick, *et al.*, nor Familo, *et al.*, disclose a histological staining process wherein the process includes Grocott's modification of Gomori's methenamine silver method.

However, Applicant has not asserted "that the prior art does not teach a staining protocol that uses a corrosive agent." Mehta, *et al.*, for instance, disclose the use of chromic acid in Grocott's method for fungi staining, as seen at page 6, line 9, page 12, lines 18-19 and in Step 12, of Table 1, at page 13, line 23, of the cited document.

Rather, Applicant has recognized and addressed problems associated with using a corrosive reagent, such as, for example, chromic acid, in a staining protocol. Specifically,

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Applicant's invention is related to replacing the corrosive reagent employed in the prior art staining process with precursors of the corrosive reagent.

Applicant has amended Claims 1, 10 and 16, as noted above.

None of the references cited in the Office Action discloses or suggests Applicant's invention as presently claimed. None of the references, recognizes or addresses problems related to the use of a corrosive reagent, such as, for example, chromic acid, in treating a biological specimen. None of the cited references, separately or in combination, discloses, contemplates, suggests or provides motivation for using the components embraced by Applicant's claimed methods.

Therefore, Claims 1-17, as presently amended, are patentable over McCormick and Familo, *et al.*, further in view of Mehra, *et al.*

#### New Claims 18-19

None of the references cited in the Office Action discloses or suggests a method of staining a biological specimen with a histological stain, wherein the specimen is treated by a process that includes treatment with a corrosive reagent, the process comprising the step of dispensing from independent liquid dispensers, onto the specimen, precursors of the corrosive reagent, wherein the liquid dispensers include at least one part fabricated from a material that is incompatible with the corrosive reagent, e.g., a plastic material, and wherein the precursors are less corrosive to the material than is the corrosive reagent, whereby the precursors combine in situ to form the corrosive reagent, thereby treating the specimen. There is no recognition in any of the documents cited of the problem addressed and solved by Applicant, and no appreciation of the advantages obtained by practicing the method of new Claims 18-19.

Therefore, Claims 18-19 are patentable over McCormick and Familo, *et al.*, further in view of Mehra, *et al.*

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CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 341-0036.

Respectfully submitted,

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MARKED UP VERSION OF AMENDMENTS

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

1. (Twice Amended) A method of staining a biological specimen with a histological stain, wherein the specimen is treated by a process that includes treatment with a corrosive reagent the process comprising the steps of:
  - (a) dispensing onto a biological specimen an oxidizer that is a precursor of the corrosive reagent; and
  - (b) dispensing onto the biological specimen [a] an acid source of hydrogen ions that is other than the corrosive reagent,whereby the oxidizer combines with hydrogen ions and the combination of oxidizer and hydrogen ions contacts the biological specimen, thereby treating the biological specimen with the corrosive reagent.
2. (Amended) The method of Claim 1 wherein the histological [staining] stain is performed by an automated histological staining instrument.
3. (Amended) The method of Claim 1 wherein the histological [staining] stain detects or characterizes microorganisms.
4. (Amended) The method of Claim 1 wherein the histological [staining] stain includes a Grocott's modification of Gomori's methenamine silver method.
5. (Amended) The method of Claim 1 wherein the acid source of hydrogen ions is selected from the group consisting of perchloric acid, perbromic acid and nitric acid.
6. (Amended) The method of Claim 1 wherein the acid source of hydrogen ions is perchloric acid.

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10. (Amended) A method for detecting the presence or absence of microorganisms in a biological specimen in an automated histological staining process, comprising the steps of:
- (a) treating the biological specimen with a staining reagent wherein the treatment comprises dispensing from separate liquid dispensers, onto the biological specimen, a source of chromate ions and [a] an acid source of hydrogen ions, the source of chromate ions and the acid source of hydrogen ions being other than chromic acid, thereby combining chromate ions and hydrogen ions, wherein the combination of chromate ions and hydrogen ions contacts the biological specimen;
  - (b) washing the combination of chromate ions and hydrogen ions from the specimen;
  - (c) staining the washed specimen with a histological stain suitable for the detection of microorganisms; and,
  - (d) detecting the presence or absence of microorganisms in the specimen.
12. (Amended) The method of Claim 10 wherein the acid source of hydrogen ions is selected from the group consisting of perchloric acid, perbromic acid and nitric acid.
13. (Amended) The method of Claim 10 wherein the acid source of hydrogen ions is perchloric acid
16. (Amended) A method of staining a biological specimen in an automated histological staining procedure, wherein the biological specimen is treated by a process comprising the steps of:
- (a) combining a source of chromate ions and [a] an acid source of hydrogen ions, wherein said source of chromate ions and said acid source of hydrogen ions are other than chromic acid; and
  - (b) contacting the combination of (a) with the biological specimen, thereby treating the biological specimen.